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Concepts, challenges and opportunities in regulatory strategy of Uttar pradesh drugs and pharmaceutical company Ltd

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Uttar Pradesh Drugs and Pharmaceutical Company Ltd (UPDPL), Lucknow is the only public sector drug manufacturing company of Uttar Pradesh. The plant functions at WHO/GMP guidelines. The challenging landscape is largely a result of the success of the biopharmaceutical industry in delivering medical therapies for many disease states, safety catastrophes from use of products post-approval; and product quality compliance issues. These have sharpened regulatory authorities' focus on product benefit/risk profiles and related stakeholders' views on cost effectiveness and patient access. The regulatory professional has to be equipped and poised to effectively guide the organization to success with a credible voice, informed strategic guidance and objective evaluation. The scope of the regulatory affairs group function spans the entire spectrum of product development, manufacturing, registration, post-marketing activities and lifecycle optimization. This span of involvement and responsibility is sometimes referred to as bench to bedside and beyond, from cradle to grave, from inception through lifecycle optimization, from laboratory to launch, etc. The regulatory team and professional hold a unique position of importance with impressive diversity in function and significant breadth and depth of responsibility. Key functional units are Product development, Chemistry, manufacturing and control, Policy and regulatory intelligence, Regulatory submission, Product labeling and Promotion and advertising which are having their own key roles and strategic elements of global regulatory contributions.

Biography

Shivendu Ranjan is in B.Tech Biotechnology Final year at the age of 21 years from VIT University, Vellore, Tamil Nadu. He has published 3 papers in peer reviewed journals. He was the Student Organizer of VIT Biosummit'12, a meet between industrialists and academia. He was Manager/ Co-Organizer of graVITas'12 (College Technical Fest). He was also student coordinator in many college tech and cultural fests. He has good presentation skills with leadership and team management skills.

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Overview: Differences in regulatory requirements for clinical trial conduct worldwide

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Regardless of the specific type of clinical research, all clinical studies follow similar steps for defining the concept, developing the protocol, conducting the study, analyzing study data, and every step in between; compliance with the guidelines given by various regulatory agencies may differ globally. Various regulatory agencies worldwide may have their own different guidance and requirements for the conduct of clinical trial. This will significantly affects the design and conduct of same clinical trials in different regions of world. Differing in requirements by regulatory agencies worldwide ultimately create significant challenges especially with multicentre clinical trial design and conduct. No complied guidelines with differences & similarities of various clinical trial conduct related requirements of different regulatory authorities across the world exist. Here review scenarios have been placed involving different regulatory authority requirements for clinical trial conduct along with some recommended viewpoints to deal with various requirements of different agencies, when consistent & appropriate worldwide viewpoints are not developed and accepted worldwide.

Biography

I, Shraddha Parmar has completed M.Pharm in Quality Assurance from NMIMS University. Curently I am working as Assistant Professor in Q.A. at Post Graduation Department of Pharmaceutical Sceinces, Sardar Patel University, Vidhyanagar, Gujarat. I have published 3 papers in reputed journals. I have attended many pharmacy related reputed conferences and presentations.

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